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South Texas Veterans Health Care System Joins Test Validation Trial of bioAffinity's CyPath® Lung

SAN ANTONIO, Oct. 23, 2018 (GLOBE NEWSWIRE) -- bioAffinity Technologies, a privately held biotech company, today announced that the South Texas Veterans Health Care System (STVHCS), which is affiliated with the federal Department of Veterans Affairs (VA) health care system, will be a clinical collection site for the Company's test validation trial of CyPath® Lung, a non-invasive test for the early detection of lung cancer.

Dr. Sheila A. Habib, director of the Pulmonary Lung Cancer Clinic at STVHCS' Audie L. Murphy Memorial Veterans Hospital, will supervise the study as the principal investigator. STVHCS will collect sputum samples from patients who have received a confirmed diagnosis of lung cancer, one of three cohorts in the bioAffinity study.

"Studies show that lung and bronchus cancers represent 20 percent of all cancers among our veteran population," Dr. Habib said. "We also know that lung cancer is difficult to detect in its early stages, and by the time our patients are symptomatic, treatment options are not as effective. A non-invasive, highly accurate and relatively low-cost assay like CyPath® will change the paradigm for the diagnosis and treatment of lung cancer not just for veterans but for all patients."

CyPath® Lung is a flow cytometric test that uses a proprietary molecule that binds to cancer cells and causes them to fluoresce in contrast to non-cancer cells. The validation study will confirm the differential characteristics between sputum samples collected from three participant cohorts, including patients with lung cancer, high-risk participants without lung cancer and healthy individuals with no or minimal smoking history who are cancer-free.

"We are pleased to have the opportunity to work closely with Dr. Habib and the VA here in San Antonio to advance our CyPath® diagnostic through our validation study," bioAffinity President and Chief Executive Officer Maria Zannes said. "Our focus on lung cancer gives bioAffinity a special connection to veterans because we know they are at significantly higher risk of developing lung cancer than the general population."

According to the Department of Defense's Office of Congressionally Directed Medical Research Programs (CDMRP), military personnel are more likely to develop lung cancer due to higher rates of smoking and increased exposure to environmental carcinogens during their service.

bioAffinity expects CyPath® Lung to enter the U.S. commercial market as a Laboratory Developed Test (LDT) to augment lung cancer screening by low dose computed tomography

(LDCT) by first quarter 2019. Although it is the current standard for early screening, LDCT has a 96 percent false-positive rate, which requires follow-up procedures to confirm a lung cancer diagnosis. By significantly increasing diagnostic accuracy, CyPath® Lung is expected to lead to improved patient survival, fewer unnecessary invasive procedures and lower medical costs.

STVHCS joins six other clinical sites – Icahn School of Medicine at Mount Sinai in New York, Summit Medical Group in New Jersey, Radiology Associates of Albuquerque in New Mexico, Waterbury Pulmonary Associates in Connecticut, Cookeville Regional Medical Center in Tennessee, and Atlantic Health Systems in New Jersey – currently enrolling volunteers for the study.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. (www.bioaffinitytech.com) is a privately held company that develops proprietary in-vitro diagnostic tests and targeted cancer therapeutics using breakthrough technology that preferentially targets cancer cells. Research, optimization and commercialization of its platform technology are conducted in bioAffinity Technologies' laboratories at the University of Texas San Antonio. The Company's initial product is CyPath® Lung, a diagnostic assay for the non-invasive detection of early-stage lung cancer.

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